

SHANNON MINERALS 26 Washington Street, 3rd Floor Morristown, New Jersey 07960
(973) 267-6980 p (973) 267-6981 f
www.shannonminerals.com

Rec'd VL
JUN 20 2005

June 17, 2005

Sent Via Fed Ex Confirmed Delivery

Victoria L. Lutwak
Division of Dietary Supplement Programs (HFS-822)
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal building
Room 4D022
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Ms. Lutwak:

The post-it note formed part of a discussion relating to the two applications, synthetic K-HCA and extract of Garcinia Cambogia.

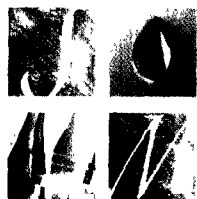
Historically Shannon Minerals has been using our own HPLC method to test the Appetrim K-HCA for the synthetic product we sell in our EU markets.

When we received the specification sheet and HPLC method from SABINSA for the extract of Garcinia Cambogia we had a discussion as to whether we should include our own method in addition to the SABINSA method but we proceeded with just the use of the Sabinsa testing method for the Sabinsa product. Since Shannon Minerals does test all incoming K-HCA shipments, we have attached our HPLC testing method (see attached PDF file). This methodology (in the attached PDF) does apply to both the synthetic and extract of Garcinia Cambogia applications. It should be added after the SABINSA HPLC page on the Extract application and before page 10 on the synthetic application.

I hope this clears up any confusion in this matter. If you need anything further please let me know.

Sincerely,

David Tourville



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5100 Paint Branch Parkway
College Park, MD 20740-3835

June 2, 2005

RE: Replacement pages for the Pre-market Notification of ***Extract of Garcinia Cambogia, (-)-Hydroxycitric Acid and Synthetically Produced (-)-Hydroxycitric Acid***

Dear Vicki,

Enclosed are the replacement pages for the smudged copies, 12 sets each already punched for insertion into the applications. Because the numbering of the pages differs from the extract to the synthetic application, we did not attempt to number these pages but hopefully the instructions below will be sufficient for the task at hand.


The first set of replacement pages is the 42 page document called, "Diet and Health Benefits of HCA" This goes in the second section of the application behind the light blue tab titled, "History of Use/Safety Evidence" It is the last part of that section (about page 38 on the Extract applications, page 41 on the synthetic applications) and ends just before the Toxicology tab.

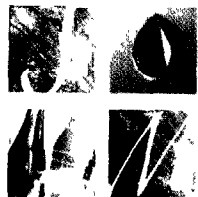
The second set of replacement pages is in Appendix C, the very last set of pages in the each of the applications. These constitute the last 12 pages of each of the applications.

Thank your for your input and help in this matter. If there are any questions or if any further information required, please contact me directly at any of the numbers below.

Tel : (973) 267-6980
Mobile: (908) 963-3986
Fax: (973) 267-6981
Email: david@brodericktourville.com

Yours sincerely,


David S. Tourville



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MAY 25 2005

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Victoria L. Lutwak
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Center for Food Safety and Applied Nutrition
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5100 Paint Branch Parkway
College Park, MD 20740-3835

May 23, 2005

RE: Pre-market Notification of ***Extract of Garcinia Cambogia, (-)-Hydroxycitric Acid***

Dear Sir or Madam,

Enclosed, please find our pre-market Notifications for our new Dietary Ingredient, *Extract of Garcinia Cambogi, (-) - Hydroxycitric Acid*, specifically Citrin K BG® by Sabinsa Corporation, pursuant to 21 C.F.R. § 190.6. for the Coolwater brand (top 3 binders) and our Burren Springs (no preservatives-next 3 binders). The second set of applications are for both brands again with synthetic HCA.

Citrin K BG® has been granted a **Certificate Of Free Sale** within the USA and for export.
See attached copy in APPENDIX B: Safety and Toxicology, Certificate of Free Sale

The notification forwards evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe by providing the Food and Drug Administration with information, including citations to, and copies of, published articles, which are the basis on which the manufacturer has concluded that the dietary supplement containing the dietary ingredient will reasonably be expected to be safe. See generally 21 U.S.C. § 350b(a)(2).

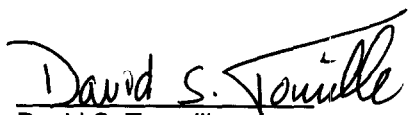
Please note our contact details below for any communication with your office:

Mr. David Tourville, Shannon Minerals Inc, 26 Washington Street, 3rd Floor, Morristown, NJ 07960.

Tel : (973) 267-6980
Fax: (973) 267-6981
Email: david@brodericktourville.com

An original and two copies of the notification are submitted.

Yours sincerely,


David S. Tourville

PREMARKET NOTIFICATION

EXTRACT OF GARCINIA CAMBOGIA (-)-HCA

SUBMITTED BY

BRENDAN O' MARA
SHANNON MINERALS LIMITED
UPPER CLARE STREET,
LIMERICK,
IRELAND

MAY 2005

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

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COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

1. NAME AND ADDRESS OF DISTRIBUTOR AND CURRENT MANUFACTURER

Distributor:

Mr. David Tourville,
Shannon Minerals Inc
26 Washington Street
3rd Floor
Morristown
NJ 07960
Tel : 1-973-267-6980
Fax: 1-973-267-6981
Email: david@brodericktourville.com

GMP Manufacturer:

Sabinsa Corporation
70 Ethel Road West, Suite 6
Piscataway, NJ 08854, USA
Tel: +1-732-777-1111
Fax: +1-732-777-1443
E-mail: info@sabinsa.com

GMP BOTTLER/PACKAGER

Shannon Minerals Limited
Upper Clare Street,
Limerick ,
Ireland.

Tel: + 353 61 418068
Fax + 353 61 418179
E-Mail brendanomara@shannonminerals.ie or willie@shannonminerals.ie

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

2. NAME AND IDENTITY OF NEW DIETARY INGREDIENT

Chemical Name: (2S,3S) –2- Hydroxycitric Acid
 Other Name: Extract of Garcinia Cambogia, (-) - Hydroxycitric Acid
 Common Name: (-) HCA, (-) -Hydroxycitrate

(See also (-) – Hydroxycitric Acid – The principal Acid in the fruits of Garcinia Cambogia Desr., Lewis and Neelakantan, Central Food Technological Research Institute, Mysore, India, March 1964) – (Appendix A)

COMPARISON OF DIFFERENT SOURCES OF (-)-HCA

Examples of such salts are; Citrin® by Sabinsa™ a Calcium salt, Citrin K BG® by Sabinsa,™ a Potassium Salt, Citrimax® by InterHealth Nutraceuticals™ a Calcium salt, SuperCitrinax® by InterHealth Nutraceuticals™ a Potassium /Calcium Salt.

	Super CitriMax®	Citrin K BG®
Loss on drying	8%	n/a
Solubility in water	>99%	>99%
PH (1 g/100 ml water)	6.0 - 9.0	6.0 - 8.5
(-)-Hydroxycitric acid	600±50 mg/g	500 mg/g
Calcium	110±30 mg/g	n/a
Potassium	160±40 mg/g	280 mg/g
Sodium	<10 mg/g	n/a
Phytosterols	0.5 mg/g	n/a
Total protein	3 mg/g	n/a
Soluble dietary fiber (by difference)	8.5%	n/a
Moisture	4.5%	5%
Microbial standards		
Total plate count	<3000 CFU/g	< 5000 CFU/g
Yeast and mold	<10 CFU/g	< 100 CFU/g
Escherichia coli	Negative	Negative
Salmonella	Negative	Negative
Staphylococcus aureus	Negative	Negative
Heavy metals		
Lead	<10 ppm	< 10 ppm
Cadmium	<0.25 ppm	n/a
Cadmium	<0.25 ppm	n/a
Arsenic	<10 ppm	< 1 ppm
Mercury	<0.25 ppm	n/a
Total Heavy Metals	n/a	<= 20 ppm

SABINSA CITRIN K BG®

Citrin K BG® has been granted a Certificate Of Free Sale within the USA and for export.
 See attached copy in APPENDIX B: Safety and Toxicology, Certificate of Free Sale.

COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

**3. DESCRIPTION OF THE PRODUCTS CONTAINING
EXTRACT OF GARCINIA CAMBOGIA, (-)-HCA.**

CONDITIONS OF USE:

PROCESSING AND METHOD OF MANUFACTURING

**BASIS FOR CONCLUSION THAT THIS DIETARY INGREDIENT IS A NEW DIETARY
SUPPLEMENT**

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COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

PROCESSING AND METHOD OF MANUFACTURING Citrin K®
Manufacturing Process

SABINSA CORPORATION

* Pharmaceuticals
* Fine Chemicals
* Cosmeceuticals

* Phytochemicals
* Herbal Extracts
* Speciality Chemicals

Corporate Office

121 Ethel Road West # 6
Piscataway, NJ 08854
Tel: (732) 777-1111
Fax: (732) 777-1443

Utah Office

750 So. Innovation Circle
Payson, UT 84651
Tel: (801) 465-8400
Fax: (801) 465-8600

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COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

Product Data Sheet

SABINSA CORPORATION

* Pharmaceuticals
* Fine Chemicals

* Phytochemicals
* Herbal Extracts

<u>Corporate Office</u>	<u>Utah Office</u>
121 Ethel Road West # 6	750 So. Innovation Circle
Piscataway, NJ 08854	Payson, UT 84651
Tel: (732) 777-1111	Tel: (801) 465-8400
Fax: (732) 777-1443	Fax: (801) 465-8600

Citrin® K

(Product Data Sheet)

Botanical Name: *Garcinia cambogia* (fam. Clusiaceae)

Product: An extract from the fruit of the *Garcinia cambogia* tree.

Source: Rinds of the fruits

Chemistry: Contains: (-) Hydroxycitric acid
28-32% elemental Potassium

% of Active Ingredient: Minimum 48% (-) Hydroxycitric acid - Lactone free

Dose: 500 mg of extract (250 mg HCA) 30 minutes to
1 hour before meals - 3 times daily.

Toxicity data: Available

Nutraceutical Applications: Appetite suppressant
Liver cholesterol synthesis inhibitor

U.S. Marketing History: Yes

Form of Supply: Standardized Powdered Extract, water
soluble

*Citrin K® is a Registered Trademark and Patented Product of Sabinsa Corporation, U.S. Patent #
5,783,603 ("Use of Potassium Hydroxycitrate for the suppression of appetite and induction of weight
loss")*

SHANNON MINERALS LIMITED

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COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION



SABINSA CORPORATION

FINISHED PRODUCT SPECIFICATION

Product CITRIN[®] K BEVERAGE GRADE (Garcinia Cambogia Extract K BG)		Specification No FP-0415-04	Supersedes None	Page Number 1 of 1
Prepared by Samar Nagar Production Manager	Reviewed by Velamurugan Manager QA/QC	Approved by Velamurugan Manager QA/QC	Effective date March 04, 2002	Review date February 2005

PLANT SPECIES /SOURCE

Garcinia cambogia / Fruits

Description

Creamy white powder, hygroscopic

Identification

1) To comply by HPLC 2) to comply for Potassium and Hydroxycitrate

Moisture Content

Not more than 5.0%

Solubility

Freely soluble in water, soluble in dilute acids and Insoluble in alcohol

pH

Between 6.0 and 8.5

Heavy metals

Not more than 20ppm

Arsenic

Not more than 1ppm

Lead

Not more than 10ppm

Tapped Bulk Density

Between 0.30g/ml and 0.60g/ml

Loose Bulk Density

Between 0.20g/ml and 0.50g/ml

Assay

- Content of Hydroxycitric Acid
by HPLC

Not less than 50.0% on a.s. such basis

- Content of Potassium by AAS

Not less than 28% on a.s. such basis

Microbiological profile

-Total Plate Count

Less than 5000cfu/g

-Yeast and Mold

Less than 100cfu/g

-*E. Coli*

Negative

-*Salmonella*

Negative

-*Staphylococcus aureus*

Negative

-*Pseudomonas aeruginosa*

Negative

-*Coliforms*

= 3/g

Country of Origin: India

REF. TEST METHOD: STP-0415-04

Citrin[®] K is Patented product of Sabinsa Corporation, US Patent No. 5,783,603

Citrin[®] K is registered trademark of Sabinsa Corporation

SHANNON MINERALS LIMITED

Page 8 of 113

COOLWATER TRIM™
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SABinsa CORPORATION

* Pharmaceuticals
* Fine Chemicals

* Phytochemicals
* Herbal Extracts

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HPLC METHOD FOR ESTIMATION OF HYDROXY CITRIC ACID

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Upper Clare Street

Limerick, Ireland

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F +353 (0)61 418179

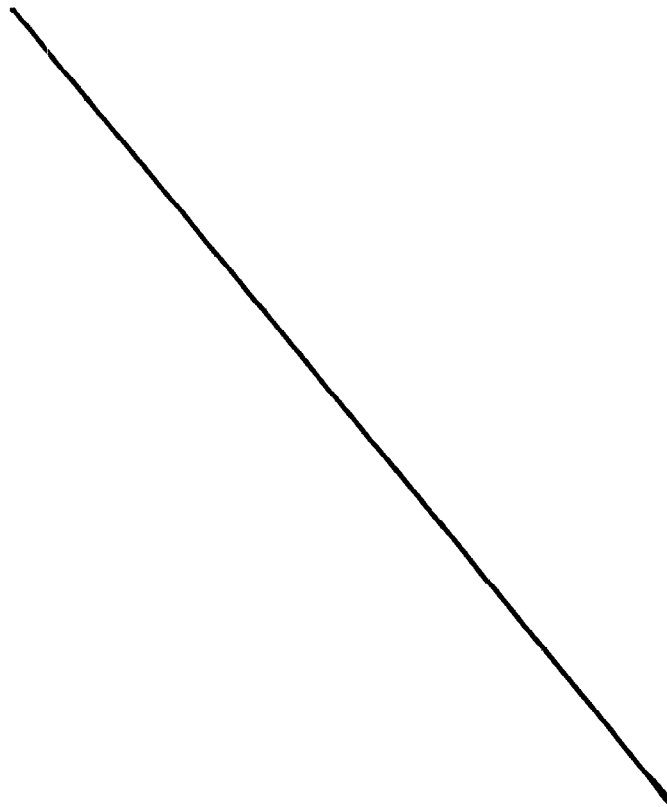
E info@shannonminerals.ie

W www.shannonminerals.ie

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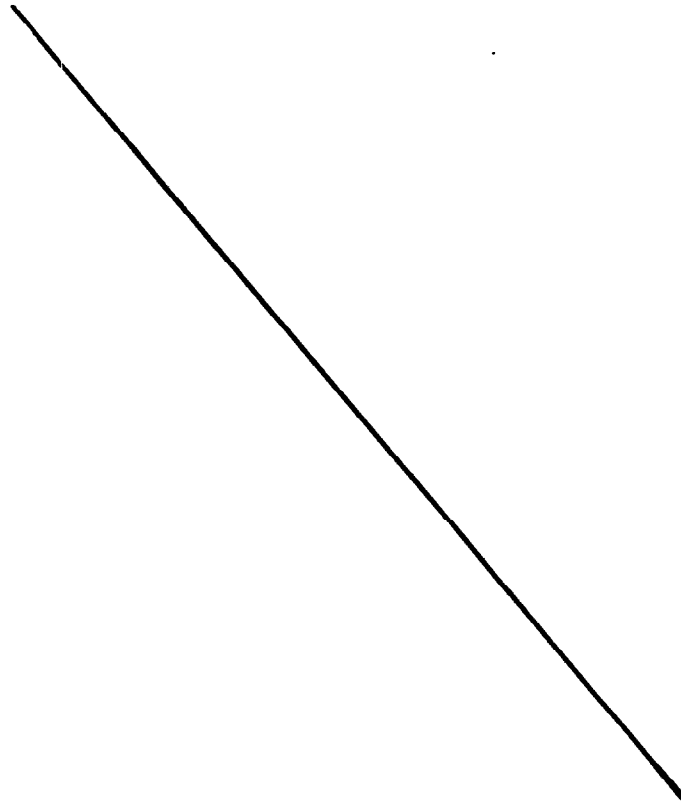
HPLC METHOD FOR ESTIMATION OF K-HCA



COOLWATER TRIM™
75 DAY PRE-MARKET NOTIFICATION

QUALITY AND MANUFACTURING PROCESS FOR TRIM™

Overall Process Flow Diagram



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